

FIGURE 1

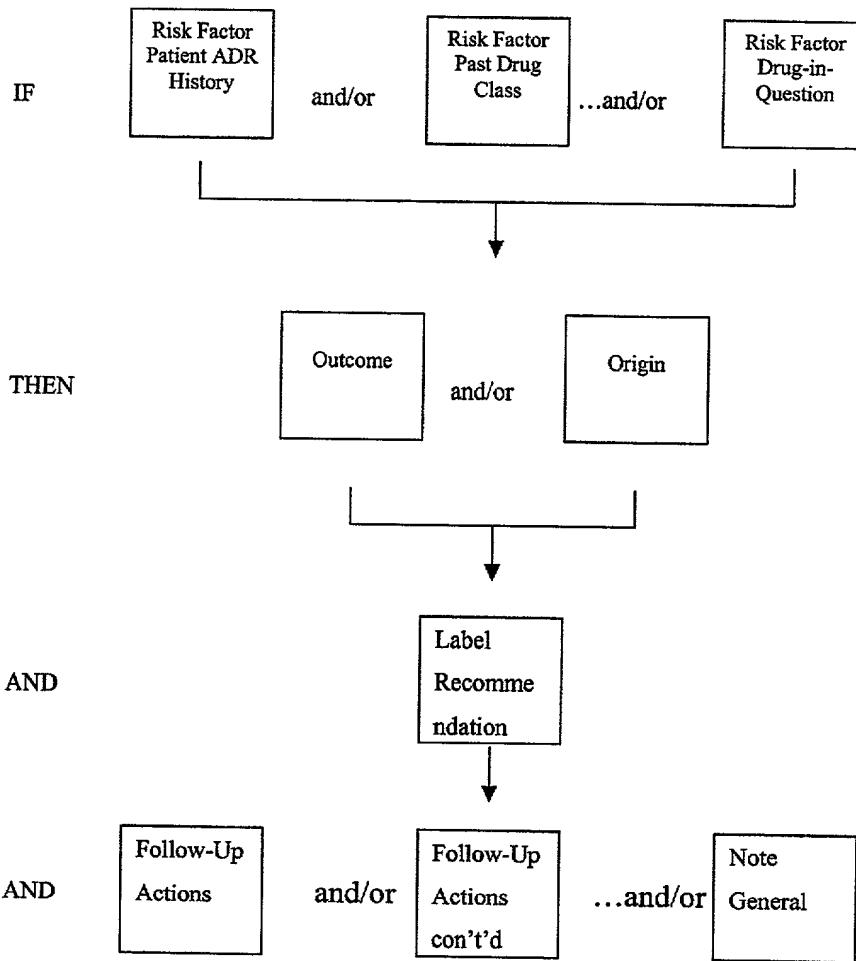


FIGURE 2

Category	Lexical Element	Lexical Element	Lexical Element
Risk factor (RF) patient history			
Risk due to past history			
RF patient ADR history	Sepsis	Hypersensitivity	Hypersensitivity
RF patient family history			
RF patient concurrent condition			
Risk due to current disease			
RF past drug		Enbrel	<i><Enbrel component></i>
RF past drug class			
RF concomitant drug			
RF concomitant drug class			
RF drug-in-question (DIQ) class	DMARD	DMARD	DMARD
RF DIQ	Enbrel (etanercept)	Enbrel (etanercept)	Enbrel (etanercept)
RF difference of gender			
RF age			
Outcome	Sepsis	Hypersensitivity	Hypersensitivity
Outcome origin			
Notes on outcome and resolution			
Prescribing action for DIQ	Contraindication	Contraindication	Contraindication
Follow-up actions			
Follow-up actions cont'd			
Conditional follow-up actions			
FUA condition			
FUA conditional action			
Instructions to patient			
Conditional instructions to patient			
ITP condition			
ITP conditional action			
What to remain alert for			
Not to be used as alternate therapy for			
Parameters to monitor			
What to test or check			
When to test or check			
Why/what to consider			
Prescribing notes to Physician			

FIGURE 3

Category	Lexical Element	Lexical Element
Risk factor (RF) patient history		
Risk due to past history		
RF patient ADR history		
RF patient family history		
RF patient concurrent condition		
Risk due to current disease		
RF past drug		
RF past drug class		
RF concomitant drug		
RF concomitant drug class		
RF drug-in-question (DIQ) class	DMARD	DMARD
RF DIQ	Enbrel	Enbrel
RF difference of gender		
RF age		
Outcome	New infection	sepsis
Outcome origin		
Notes on outcome and resolution		
Prescribing action for DIQ	Continue	Discontinue
Follow-up actions	Monitor closely	
Follow-up actions cont'd		
Conditional follow-up actions	Discontinue if new infection becomes serious	
FUA condition		
FUA conditional action		
Instructions to patient		
Conditional instructions to patient		
ITP condition		
ITP conditional action		
What to remain alert for		
Not to be used as alternate therapy for		
Parameters to monitor		
What to test or check		
When to test or check		
Why/what to consider		
Prescribing notes to Physician		

FIGURE 4

Figure 5: Sample of mapping a conditional text statement to a rule structure, using dictionary terms

Label Text:

Celebrex should not be given to patients who have demonstrated allergic-type reactions to sulfonamides.

Risk Category		
Risk Factor Patient past history		
Risk Factor Patient ADR history	Allergic-type reactions	
Risk factor Patient family history		
Risk Factor Patient concurrent condition		
Risk factor Past drug		Sulfonamides
Risk factor Past Drug Class		
Risk Factor Concomitant Drug		
Risk Factor Concomitant drug class		
Risk Factor Drug-in-Question Class		
Risk factor Drug-in-Question	Celebrex	
Outcome		
Outcome Origin		
Additional Notes on Outcome and Resolution		
Prescribing Action for Drug-in-Question	Contraindicated	
Follow-up Actions		
Follow-up Actions cont'd		
Conditional Follow-up Actions		
FUA Condition		
FUA Conditional action		
Instructions to Patient		
Conditional Instructions to Patient		
ITP Condition		
ITP Conditional action		
What to Remain Alert For		
Not to be used as Alternate Therapy For		
Parameters to Monitor		
What to Test/Check		
When to Test/Check		
Why/What to Consider		
Additional Prescribing Note to Physician		
Note General		

Do not use this drug if you are allergic to it. If you have had an allergic reaction to this drug, tell your doctor or pharmacist before taking it again.

Figure 6: Sample of mapping a complex conditional text statement to a rule structure, using dictionary terms

Label Text:

Celebrex should not be given to patients with the aspirin triad. The symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAID's. Emergency help should be sought in cases where anaphylactoid reactions occur.

Risk Category				
Risk Factor Patient past history				
Risk Factor Patient ADR history		Rhinitis; rhinitis with nasal polyps; severe bronchospasm		
Risk factor Patient family history				
Risk Factor Patient concurrent condition				
Risk factor Past drug		Aspirin triad		
Risk factor Past Drug Class		NSAIDs		
Risk Factor Concomitant Drug				
Risk Factor Concomitant drug class				
Risk Factor Drug-in-Question Class		NSAIDs		
Risk factor Drug-in-Question	Celebrex			
Outcome				
Outcome Origin				
Add'l Notes on Outcome and Resolution	Potentially fatal bronchospasm			
Prescribing Action for Drug-in-Question				
Follow-up Actions			Inform patients	
Follow-up Actions cont'd				
Conditional Follow-up Actions				
FUA Condition				
FUA Conditional action				
Instructions to Patient				
Conditional Instructions to Patient		If anaphylactoid reaction seek emergency help		
ITP Condition	Anaphylactoid reaction			
ITP Conditional action			Seek emergency help	
What to Remain Alert For				
Not to be used as Alternate Therapy For				
Parameters to Monitor				
What to Test/Check				
When to Test/Check				
Why/What to Consider				
Additional Prescribing Note to Physician				
Note General				

Figure 7: Sample of reverse tracing mapping to original label

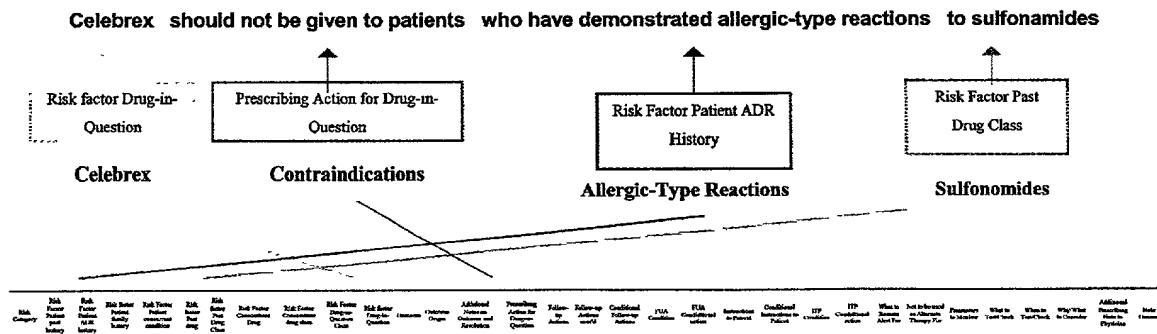
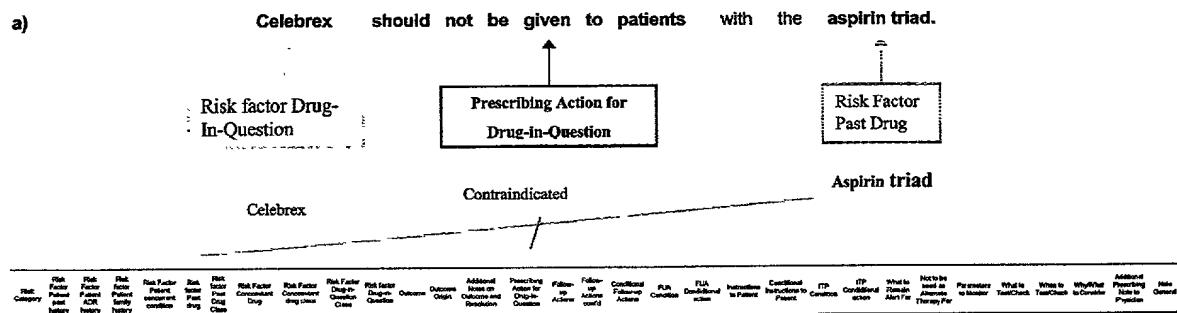


Figure 8: Sample of reverse tracing mapping to original label, in three parts

Label text: Celebrex should not be given to patients with the aspirin triad. The symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAID's. Emergency help should be sought in cases where anaphylactoid reactions occur.

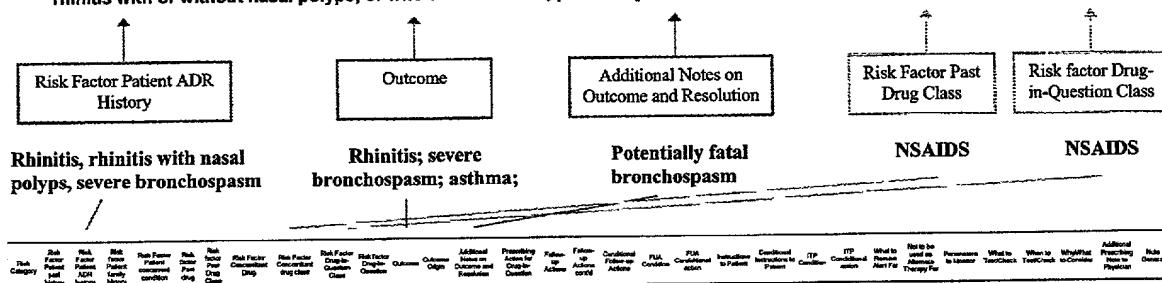
a)



Ther Category	Risk Factor Past history	Risk Factor Past ADR history	Risk Factor Past concurrent condition	Risk Factor Past drug	Risk Factor Drug Class	Risk Factor Concurrent drug	Risk Factor Concurrent drug class	Risk Factor Question	Risk Factor Question Class	Outcome	Outcome Origin	Additional Notes on Outcome and Resolution	Prescribing Action for Drug-in-Question	Follow-up Action	Conditional Action	PIN Condition	Flu Condition	Interventions	Conditional Interventions	IP Condition	What is Alert For	Notes to User	What is Task/Check	What is Why/What	Additional Prescribing Actions	Notes General
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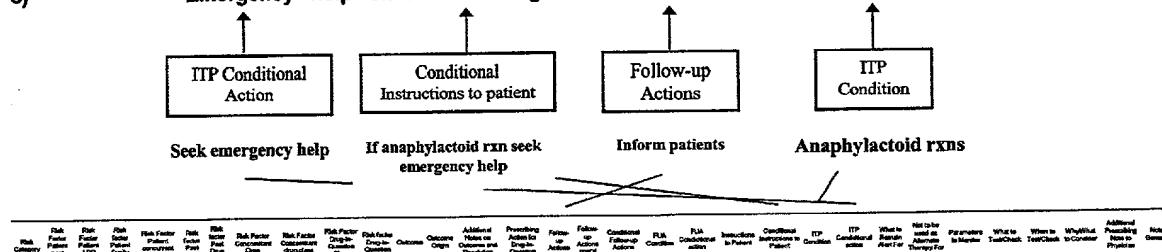
8b)

The symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAID's.



c)

Emergency help should be sought in cases where anaphylactoid reactions occur.



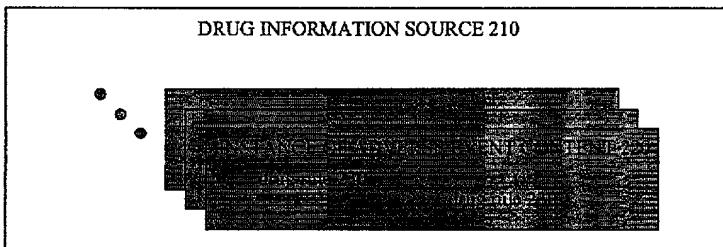


FIGURE 9

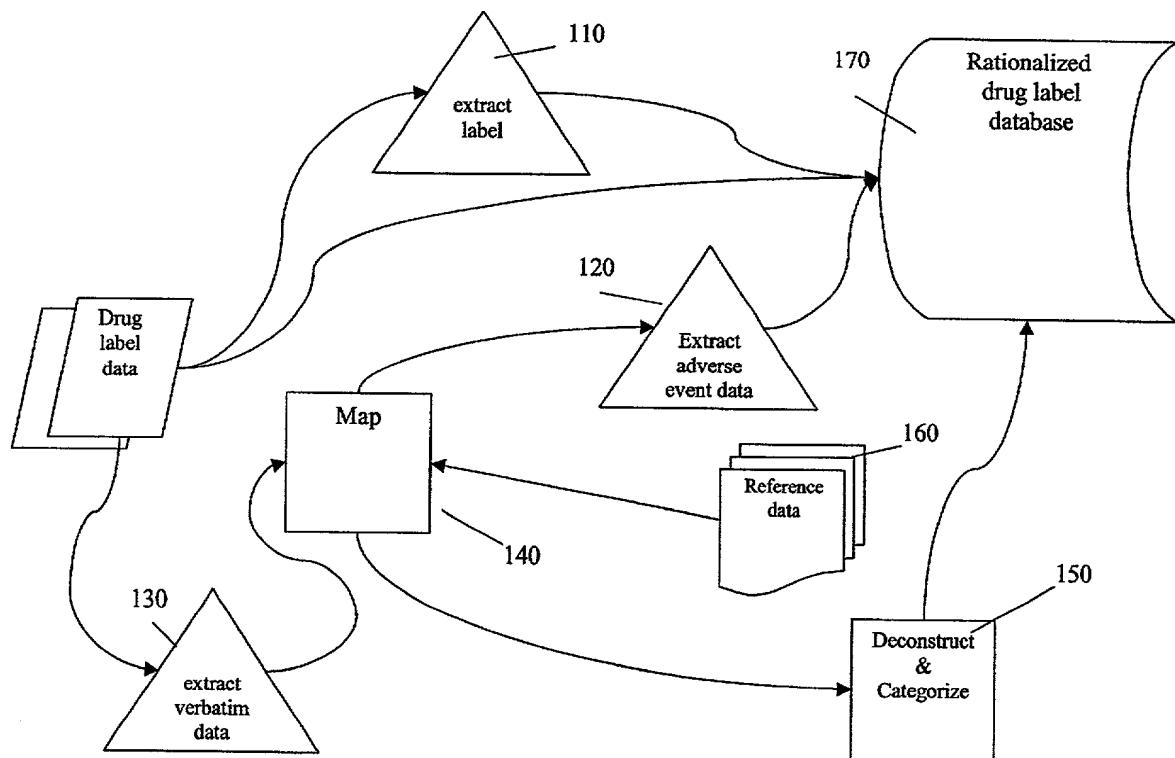


Figure 10